Remarks

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RE:	Patent Application for Schepers	: Date:	Sept 9, 2004
Serial No.:	09/868,744	: Group No.:	1638
Filed:	Jan. 09, 2002	: Examiner:	Metha Ashwin
For:	Genetic Modification of Compositae	:	

Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

Claim Objections

In the first paragraph, of the section numbered 1, the Examiner objected to claim 3 as failing to comply with the sequence rules of 37 CFR 1.821-1.825 as the claim did not identify the sequence identifier. The first claim, as now amended, indicates that this sequence identified as Seq. ID. No. 1.

In the second paragraph, of the section numbered 1, the Examiner objected to claims 4 and 10, as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner is asked to reconsider this objection. Claim one only claims that the DNA sequence expresses RNA; however, claims 4 and 10 require that the RNA expressed codes for the production of a heterlogous protein. This does further limit the claim. As the specification teaches on pages 3 to 4, RNA may be of two main kinds: either a sequence which expresses mRNA which is translated into protein or alternatively a sequence which produces RNA which is not translated inot protein. Thus these two claims do further limit claim1, as in both claims, the claim is limited to an RNA that is coding for the production of a protein. Since these claims are limitations of claim 1 or because claim 1 has been amended as the Examiner suggested, removal of "heterlogous", the Examiner is requested to remove this objection.

In the third paragraph in section 1, claims 5 and 13 are objected to by the Examiner, as not further limiting the subject matter of a previous claim. However, the applicant believes, that the Examiner should also remove this objection.

In the first paragraph on page 3 in section 1, claim 16 is objected to as failing to further limit. Claim 16 is directed to a vector but has been amended to further define the construct of claim 1 in method claim language. Claim 16 does limit claim 1, as claim 16 adds limitations to the method of claim 1.

The Examiner has indicated that the use of the terms heterologous and homologous are not clear. However, the Examiner does indicate that the specification actually does teach on page four that heterologous genes may be used to up or down regulate homologous genes, which indicates that heterologous genes are not endogenous to the host plant while homologous genes are endogenous to the plant. But then the Examiner states that these are unclear, as they are not defined.

In fact these terms are definite and they are defined. Terms can be defined by providing a written definition or they can be defined by there contextually usage in a document. In this application, the terms, heterologous and homologous, are contextually defined. To be used in the manner that these terms were in the specification defines "heterologous" to be not endogenous to the plant and homologous as endogenous to the plant. In Webster's ninth new Collegiate Dictionary , heterologous is defined as "derived from a different species"<~DNAs> <~transplants>. Or in this case not endogenous to the host plant.

In Webster's ninth new Collegiate Dictionary, homologous has two different definitions. One of these two definitions that fits within the contextual use of the term in the specification. This definition also substantially parallels the definition of heterologous. This definition is: "derived from or developed in response to organisms of the same species."

The other Webster definition also works to define the term, homologous but is more circular. This second definition is: "exhibiting biological homology." To understand this definition the term "homology", also needs definition. Homology is defined in its first definition as: " a similarity often attributable to common origin." Thus this applications the contextual use of the terms which defines them to mean: endogenous to the host plant and not endogenous to the host plant and the standard dictionary definitions are in perfect harmony. The terms are not indefinite and are used in a manner supported by usage of the terms as shown in Webster's Dictionary. The applicant requests that the Examiner remove this rejection. The applicant also notes that this term has been removed from claim 1 and claim 9 as previously suggested by the Examiner. The use of these terms in the remaining claims should be definite.

In claim 7 the recitation of homologous was alleged to make the claim indefinite. The applicant's attorney believes that the discussion above and the amendment to claim one should have clarified the use of this language and therefore the language is not

amended in claim 7. The Examiner's suggestion to remove "a" and insert "said" has been implemented in the amendment of claim 7.

The recitation in claim15 has been deleted. The language concerning "adapted' has been amended in claims 9-11 13-16 (Claim 15 was deleted).

The Examiner's suggestion concerning claim 16 has been followed and the recitation has be deleted.

Claim Rejections Under 35 USC § 112

In the first paragraph, of the section numbered 2, the Examiner rejected claims 1, 3-21 under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 1 recites the modified gene in lines 2-3 and the Examiner indicates there is no antecedent basis. Additionally, the recitation "of a reduce tendency to silencing" renders the claim indefinite as this language is not clear. This language has been removed.

This claim has been amended to remove the "modified gene..." language and additionally this claim has been amended to remove the "adapted" language. These amendments should clarify the scope of the claims.

In paragraph 3, Claims 1 and 3 –21 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the breadth of all actin2 promoters are not described in the specification. The claims have been amended to include the limitation of claim 2 within claim 1. Thus the actin 2 promoter as amended in the claim should overcome the 112 rejection. The Examiner is kindly asked to remove this rejection.

In paragraph 4, Claims 1–21 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the claim reads on transformation of all members of the *Compositae* family. The claim has been amended to comprise lettuce and sunflower. These two *Compositea* are described within the specification on pages 6 and 10-11. The claim as now amended should overcome this rejection and the Examiner is requested to remove this rejection.

Claim Rejections

In paragraph 5, Claim 16 was rejected under 35 U.S.C. § 102(b) as being anticipated by AN et al. The amendments to claim 16 to depend from claim1 should remove the Examiner's rejection to claim 16.

In paragraph 6, Claims 1, 4-11, 13-15, 17,18, 21 were rejected under 35 U.S.C. §102(e) as being anticipated by Barbour et al. '467. In U.S. patent 6,670,467 ('467) Barbour et al., the basic teaching of this patent is that 4 maize promoters have been identified. These promoters are for tissue specific of constitutive promoters for genes encoding actin-2, enolase, Gos-2 and L41. The patent then alleges that it teaches a

method that comprises transforming a plant cell with a nucleotide sequence in a plant and operatively linking it to at least one of the promoter sequences disclosed and regenerating a stably transformed plant for the transformed plant cell. However, there is no actual experimental evidence of any of these alleged promoters in any actual plant. The only example is a hypothetical example. There is no evidence in this patent that these alleged promoter sequences actually are promoters or are actually working as promoters in association with genes. In fact, the specification points out that there is no significant match to other transcriptional promoters when checked on the GCG blast N analyses of the Gene Seq database. Gene sequence database test – column 18, lines 62-67. This patent does not enable anything concerning lettuce or sunflowers. It simply supplies at column 15, lines 9-64, every type of article on transformation. Then a laundry list of crops that these maize promoters may work in is given in Column 16, lines 9-67, listing 116 different species (maybe 25 are repeated). There is no teaching of the claimed invention as now amended. The Examiner is requested to remove this objection.

Claims 1, 4-21 were rejected in Paragraph 7, under 35 USC § 103(a) over '467 and Hartman. The Examiner is requested to remove this rejection as claim 2 which was not rejected has been amended into claim 1. The amendment should overcome this rejection and the Examiner action to remove the rejection is kindly requested.

In Paragraph 8, claims 1-21 were rejected under 35 U.S.C. § 103(a) over a list of sited art. In the Examiner's discussion he indicates that one would have been motivated to use different promoters including the act2 promoter. The applicant does not disagree that this promoter was known. But what is not shown is any motivation or reason to try this promoter in the lettuce and sunflower family. Each of these articles teach something. But the articles in combination do not motivate anyone to use the claimed invention. In review the Scott and Vick article that was published in 1993 teaches that a sunflower can be transformed. The experimental evidence indicates that the T1 (or the second generation) of transgenic plants have less evidence of foreign DNA (i.e. the transgene). This problem has been referred to, by many scientists, as gene silencing. These authors do not identify the problem by this term. The article does not mention which promoter was used throughout the transformation process. Nor does it suggest that the invention be used.

The article on transforming lettuce was written by I.S. Curtis et al. This article does indicate which promoters were used in the vectors transformed into the lettuce. One vector included the nos, NPTII, nos gene. The first "nos" refers to a nopaline synthesase promoter, NPTII refers to a kanamycin resistant gene and the last "nos" refers to the nos terminator. In addition to this the construct includes the CaMV 35S(promoter), Gus (gene), and an intron as a reporter gene. The promoter in this instance is the Cauliflower mosaic virus 35 S promoter that drives a Gus gene that shows bright blue spots when it is expressed in the cell.

Again in this article, in the second to last paragraph on page 1448, the article makes clear that some positive R1 plants seedlings showed NPTII positive teaching in the

assay and some also showed Gus (with the CaMV35s promoter) positive plants. However, this article also indicates that other R1 failed to express Gus even though it was detected by Southern Blot hybridization. But there is no teaching or suggestion that the claimed invention would be useful.

US patent 6,084,164 ('164) to Bidney is dated March 25, 1996 and issued on July 4, 2000. The teaches that transformed sunflower material can be grafted on to nontransgenic material for the production of some transgenic material. This patent basically teaches that the antisense expression of a Stearoyl-ACP desaturase gene in sunflower results in more than a four-fold increase in seed stearate. The vector used was the napin promoter from the napin gene from Brassica napus. In Figure 1, the plasmid shows that the 35s promoter is being employed to drive the NPTII gene in Column 6, lines 29-41, there are listed a number of preferred promoters. The preferred promoters are the seed tissue promoters. Actin 2 is not in this list of materials. Additionally, the patenet directs persons to use promoters that are expressed during embryogenic and oil biosynthesis (see column 6, lines 42-58). This patent seems to indicate in column 11 that T2 seed were used for the initial fatty acid analysis however there is no evidence provided that shows what the result of the analysis was. In column 12 the patent specification on lines 15 -25 shows that the DNA sequence was detected in the T0's progeny (TI). The specification indicated that eight plats were transformed and the transgenic seeds contained light levels of stearate and lower levels of oleate compared to seed from untransformed plants. However, there is no indication of what number of T2, T3 nor T4, etc. plants were evidencing expression of the gene. There is no use of the actin 2 promoter in this patent.

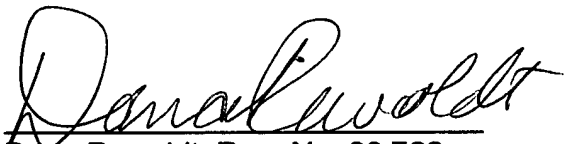
U.S. patent 5,633,437 ('437) did not teach the use of the Actin 2 promoter. This patent only taught that use of the 35S promoter. In a broad general statement in that last paragraph of the detailed description, prior to the Experimental heading, it indicated that the crop plant of particular interest includes soybeans, cereal crops , such as maize; tomatoes and sunflower. Thus sunflower is not shown as transformed. Sunflower is only indicated as being different from the other interesting crops in the general list. Thus transformation of sunflower was simply a possibility, not a teaching. No transformation of plants is shown in the examples. The patent alleges that plants can be transformed with a new cocklebur gene that resists a class of herbicides wherein the acetolactate synthase (ALS) is the site of action.

In U.S. patent 6,670,467 ('467) Barbour et al., the basic teaching of this patent is that 4 maize promoters have been identified. These promoters are for tissue specific of constitutive promoters for genes encoding actin-2, enolase, Gos-2 and L41. The patent then alleges that it teaches a method that comprises transforming a plant cell with a nucleotide sequence in a plant and operatively linking it to at least one of the promoter sequences disclosed and regenerating a stably transformed plant for the transformed plant cell. However, there is no actual experimental evidence of any of these alleged promoters in any actual plant. The only example is a hypothetical example. There is no

evidence in this patent that these alleged promoter sequences actually are promoters or are actually working as promoters in association with genes. In fact , the specification points out that there is no significant match to other transcriptional promoters when checked GCG blast N analyses of the Gene Seq database. Gene sequence database test – This patent fails to teach instead it provides laundry list of information. In column 18, lines 62-67, column 15, lines 9-64, simply lists every type of article on transformation; column 16, lines 9-67, lists crops, vegetables, 116 different species (maybe 25 are repeated);Column 16, lines 55-58, lists the preferred crops as 12, part of particular interest are grain plants, which include 6 and also oil seed plants, which include 9.; and leguminous plants which include 14. Then the laundry list starts pointing in a direction and states in Line 55 the more preferred crops as being corn and soybean, yet more preferably corn lines 59-67. A patent that provides nothing more then a laundry list does not even teach something that is reasonable to try. Under this patent everything with every transformation method available could be tried. This is not a teaching or a suggestion to try the present invention.

The combination of these articles does not render claim 1 as obvious. The Examiner is requested to remove the rejection.

Respectfully submitted,



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